Ethics briefings

Retention and use of human tissue

Retention and use of cadaveric tissue has a troubled history in the UK and in Australia.[1] In the UK, in the aftermath of the Bristol and Alder Hey inquiries of the 1990s,[2] some 2000 claimants participated in a mass legal action against the National Health Service (NHS) in January 2004. They argued for better compensation for the trauma they suffered upon discovering that tissue from their deceased children had been removed and stored without their authorisation. These families reportedly refused an initial compensation offer of £1000, on the grounds that parents involved in the higher profile Alder Hey case had been offered £5000.[3] Thus, the High Court was given the unenviable task of determining what constituted equitable recompense in highly emotive cases.

Although removal of tissue from deceased children without parental consent is recognised to be unacceptable, it has often been assumed that use of ''discarded'' or ''leftover'' tissue from living people—particularly when anonymised—raised no ethical issues if used for education or research instead of being incinerated. Tissue such as tumours removed from adults and children as part of their diagnosis or therapy has traditionally been used for research, education, audit, and quality assurance without specific donor consent. Its use for audit and quality assurance continues to be seen as uncontroversial but the current expectation is that living donors (or parents of young children) must be specifically asked to indicate at the time of agreeing to removal of tissue whether their material can be used for research or education after its diagnostic value for them is exhausted. This was the view expressed by the British Medical Association (BMA) in 2002 in its response to the government consultation document, *Human Bodies, Human Choices*[4] and the Department of Health subsequently published similar advice in 2003.[5] Some argued, however, that there was no obvious moral distinction between public health purposes such as audit and use of discarded tissue to teach future doctors, and that since the material would otherwise be treated as hospital waste, using it for research or education for the public good should not require donor consent.

Nevertheless, in the wake of disquiet following the public inquiries of the 1990s, it was inevitable that the requirement for consent from living donors would be one of the provisions in the UK government's Human Tissue Bill, published in December 2003. The consistent focus in the bill was on informed consent to tissue use. In particular, there was emphasis on competent donors of all ages making their own decisions during their lifetime (including by means of advance statements and by appointing representatives to decide for them after death). The published bill, however, made no provision for proxy decision makers who might authorise the use of leftover tissue from mentally incapacitated adults, although amendments to that effect were suggested in its early passage through the House of Commons. The absence of such a clause would mean that research into diseases causing mental incapacity could be hindered by the obligation to destroy all tissue left over from treating such patients.

The bill intended to regularise the retention and many uses of tissue—transplantation, audit, research and education—from both living and dead patients in a single piece of legislation for England, Wales, and Northern Ireland. Use of cadaveric material for coroners' purposes was exempt. Scotland took a more piecemeal approach. The Scottish Executive has consulted separately on postmortem examination, anatomical dissection, and use of tissue. (Draft legislation for Scotland is still awaited). Throughout the UK it is expected that living individuals will increasingly make advance decisions themselves about the future use of their tissue and organs, including for transplantation, rather than leaving the matter to be decided by relatives in the emotive atmosphere of the potential donor's death. The BMA, however, argued that requiring specific consent from donors for the use of tissue in research and education need not preclude the possibility of a ''presumed consent'' system for organ transplantation.[2] Throughout the passage of the bill through Parliament, the BMA lobbied for this amendment.

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Regulating assisted reproduction in Italy

Gone are the days when a single woman considered ''too old'' for treatment in the UK could simply go to Italy for treatment. In late 2003, in an attempt to rid the country of its reputation as the ''Wild West of assisted reproduction'' the Italian Senate passed one of the most restrictive laws on assisted reproduction in Europe. The reproduction bill, which at the time of writing still had to return to the lower house but was expected to be approved without substantial revision, was described by the chairman of the European Society of Human Reproduction and Embryology (ESHRE) as: ''unethical, deplorable, and a potential disaster for women'' (European Society for Human Reproduction and Embryology press release: European experts slam new Italian fertility rules—''Disaster for women'' says ESHRE chairman, 13 December 2003). It restricts access to assisted reproduction to heterosexual couples in a stable relationship within the normal reproductive age range and prohibits the creation of more embryos than will be replaced in the treatment cycle—up to a maximum of three. It prohibits embryo research, gamete donation, surrogacy, and the storage of embryos (although surprisingly it permits storage of oocytes—which most countries still consider to be an experimental technique). The European Society of Human Reproduction and Embryology has argued that freezing of oocytes, rather than embryos, will subject women to a procedure that is of low efficacy and about which there are still safety concerns.

Payment to, and anonymity of, gamete donors

The issue of payment to, and anonymity of, gamete donors returned to the spotlight in late 2003. One Australian fertility clinic addressed the shortage of donors—exacerbated by imminent changes to permit the release of identifying donor information—by advertising in a Canadian student newspaper. Would-be sperm donors were offered free travel to Australia, two weeks' accommodation, and a daily allowance. Candidates were required to be fit,

healthy, between 18 and 40, to attend two counselling sessions, and to undergo blood and semen analysis. The package was estimated to be worth around AU$7000 (US$5180).[6]

In the UK, debate focused on the offer of ''treatment services'' in exchange for egg donation. The Human Fertilisation and Embryology Authority (HFEA) permits ''egg sharing'' whereby a woman receives reduced cost in vitro fertilisation (IVF) treatment in exchange for donating a proportion of the eggs collected, subject to strict guidance.[7] A modification of this scheme however, known as ''egg giving'', raised concerns. The situation is similar, in that a woman receives treatment services at reduced cost in exchange for donation but under egg giving, all of the eggs collected in the first stimulation cycle are donated. This is followed by a second cycle where all of the eggs are kept and used by the donor. Following a review of egg giving, the HFEA decided it was unacceptable to subject women to two cycles of stimulation with the inherent risks, purely for financial gain. Therefore, in December 2003 it advised clinics not to practise egg giving (Human Fertilisation and Embryology Authority press release: HFEA issues guidance on egg giving, 1 December 2003).

In January 2004 the UK government announced its plan to introduce regulations to remove anonymity from future gamete donors with effect from 1 April 2005. The new provisions will not apply retrospectively.

United Nations and cloning

Attempts to draw up a UN treaty banning human reproductive cloning have been delayed after it proved impossible to agree on the scope of the ban. Two opposing resolutions were proposed, one to ban all ''cloning'' technology, including so called ''therapeutic cloning'' (research into the use of cell nuclear replacement to develop compatible tissue for treatment) and the other proposing a ban on reproductive cloning only. Instead it was agreed to delay a decision until September 2004.

Europe: abortion

Ethics briefings has previously drawn attention to the fact that aspects of European abortion legislation are under challenge.[8] In December 2003, Thi-Nho Vo, a French national, launched an appeal for the European Court for Human Rights to accept a fetus's right to life under article 2 (right to life) of the European Convention on Human Rights.[9] Thi-Nho Vo was six months pregnant when her amniotic sac was erroneously pierced by a doctor following a mix up with another patient who was due to have a coil removed. As a result a therapeutic abortion was necessary. The doctor attending Thi-Nho Vo was subsequently charged with unintentional homicide, then acquitted, then convicted and sentenced. The conviction was finally reversed by the Cour de Cassation (France's highest court) which refused to consider the fetus as a human being entitled to the protection of the criminal law. Thi-Nho Vo took the case to the European Court for Human Rights, maintaining that France has an obligation to pass legislation making such acts a criminal offence based on article 2. A decision on the admissibility of the case was pending at the time of writing.

US: mentally ill death row inmate executed in Arkansas

On 6 January 2004, Charles Singleton, a convicted murderer suffering from paranoid schizophrenia, was judicially executed in Arkansas, USA.[10]

Singleton was placed on death row in 1979 following conviction for murder. Subsequent to his sentencing, the US Supreme Court developed the law further on medical treatment, and competence for execution, of mentally ill inmates. In 1986 ''the execution…of those who are unaware of the punishment they are about to suffer and why they are to suffer it'' was forbidden[11]; in 1990 it was ruled that antipsychotic drugs may forcibly be administered to ''a prison inmate who has a serious mental illness…if the inmate is dangerous to himself or others and the treatment is in the inmate's medical interest'',[12] and in 2003 it was ruled that where charges against a defendant are serious, the government's essential interest in bringing a defendant to trial outweighs his significant liberty interest in avoiding unwanted medication,[13] although it was noted that ''[A]n entirely different case is presented when the government wishes to medicate a prisoner in order to render him competent for execution'' (United States *v* Sell,[13] para 571).

Consequently, Singleton's legal case and medical care have been subject to review during his 25 years of imprisonment. Despite a history of forced administration of antipsychotic medication, prior to his execution he was taking this voluntarily. It is reported that in Singleton's case execution was desired; he ''welcomed his execution because he was tired of living with mental illness''.[14]

A considerable body of medical opinion, including that of the BMA, opposes the direct involvement of doctors in judicial executions but doctors' indirect involvement is more complex. Doctors' roles in assessing fitness or providing treatment in order to make the prisoner fit for execution are—for example, highly contentious. This case has highlighted the tension since if doctors administer treatment intended to benefit the patient, it will, if successful, render him competent for execution. In 2001, the BMA provided detailed discussion on the involvement of doctors in judicial execution, and their role in administering medication that leads to competence to be executed, in *The Medical Profession & Human Rights: Handbook for a Changing Agenda*.[15]

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